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Expert Opinion - K V Venugopalan

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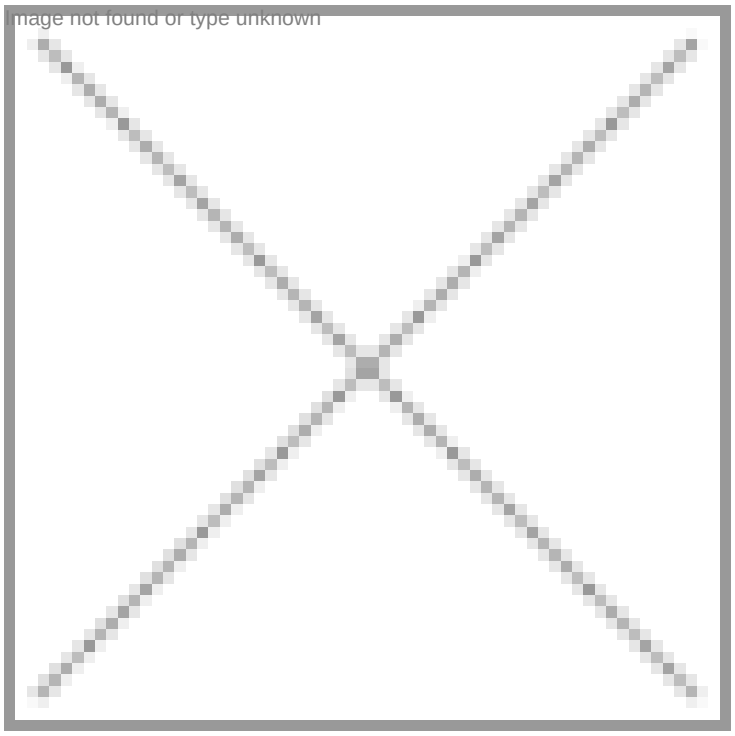

CHROMATOGRAPHY

Trends in HPLC sphere

LC market in India was about $240 million including after market and service in 2011

Over the past 30 years, high performance liquid chromatography (HPLC) has become one of the most widely used technologies in laboratories worldwide. This is due to the fact that HPLC is a dynamic and versatile technique. It is dynamic in its scope of application from capillary scale to preparative scale and it is versatile in the range of detection techniques that can be associated with it, providing analytical capabilities over a broad spectrum of compounds.

Pharmaceutical research for new drugs and delivery systems is probably the single largest application area for liquid chromatography. HPLC systems are also used in various other industries including petrochemicals, pesticides, cosmetics, power generation, food quality and safety, chemical materials, and environmental testing. Propelled by the need to meet increasing scientific and business challenges, liquid chromatography has evolved over the years. Innovations in the area of separation chemisty, detection systems, and data handling are noteworthy.

At a time when many scientists have reached separation barriers and are pushing the limits of conventional HPLC, ultra performance liquid chromatography (UPLC) presents the possibility to extend and expand the

utility of this widely used separation science. ACQUITY Ultra Performance LC Systems introduced by Waters in 2004 take advantage of technological strides made in particle chemistry performance, system optimization, detector design, and data processing and control. When taken together, these achievements have created a step-function improvement in chromatographic performance. The UPLC/UHPLC technique has gained wide acceptance in the laboratory due to its ability to provide more information per unit of work as it fulfils the promise of increased speed, resolution and sensitivity for liquid chromatography. As per SDI estimate UPLC is the fastest growing LC market segment and worldwide market in 2011 was dominated by Waters (60 percent) followed by Agilent (17 percent) and Shimadzu (eight percent).

HPLC market

In 2011, LC market in India was about $240 million including after market and service, representing close to 20 percent of the total analytical instrument market of $1.2 billion and projected to grow between 10-15 percent, depending upon the external economic conditions. This amounts to approximately 4000 LC systems (including UPLC systems) and more than 100,000 columns and large quantities of sample preparation products. After market is about $80 million (accessories and supplies including columns and sample preparation products) and services of approximately $65 million in 2011. Waters leads the market followed by Shimadzu and Agilent and the top three companies hold more than 80 percent of the Indian HPLC initial systems market.

With an installed base of over 30,000 active HPLC systems across the country, majority of them operating 24/7 in the generics pharma sector, India would consume approximately 100,000 to 120,000 columns per year.

The rapidly growing bioanalytical sector (CRO) alone consumes around a million sample prep devices, while the overall consumption of vials is difficult to estimate but is expected to add up to several million. Given this huge potential, close to $80 million, it is not surprising that almost all column and sample prep manufacturers are present in the country either directly or through distributors. Some of the significant players listed alphabetically are Agilent, Daicel, GL Sciences, Grace, Machery Nagel, Merck, Phenomenex, Sigma Aldrich, Thermo, Waters, Whatman, and YMC.

Market segments and growth drivers

The pharmaceutical and life science market are, by a considerable margin, the largest individual sources of demand, making up more than 65 percent of the total market. R&D labs, method development, and QA/QC are the main areas where LC systems are used extensively. The public sector, consisting of academic and government labs, forms another 13 percent of the market. Government expenditures on academic and research have grown along with the GDP of the country, and several important initiatives are leading to rapid growth in the HPLC market including pharmaceutical development, food and environment, chemicals and biotechnology. CSIR, ICAR, ICMR, Food and Drug testing labs, Pollution Control boards, DBT, and DST form the major users of LC systems.

Opportunities and challenges

Indian pharmaceutical industry contributes more than 65 percent for the HPLC market and continues to grow in spite of current economic conditions. Driven by top 25 companies in this sector whose export business constitutes more than 75 percent of their total turnover, this segment is poised to grow even more in the coming years as many blockbuster drugs are going off patent. CROs, government labs, food safety, and environmental laboratories are other markets that provide growth opportunities for the Indian analytical industry.

Today's users demand superior product at the lowest possible cost, where cost is not just the initial purchase cost but also cost of ownership, operation and maintenance. They also demand excellent, effortless, less expensive and hassle-free service to remain loyal to a particular vendor and all these demands seems to be conflicting. Even though vendor-switching is not easy due to regulatory and training issues, overall cost and support issues can make it easy, particularly in a challenging economic environment.

A modern analytical laboratory faces a variety of regulatory and operational challenges including operating in compliance with cGMP and other applicable industry regulations, asset optimization, consistently generating reliable and trustworthy data, minimizing errors, and levels of retesting and waste. Intellectual property and

knowledge management are other important challenges of growing organizations.

HPLC Market Trends

Market	% share
Pharma & Life Scienes	65
Academia	6
Chemical Materials	8
Govt. Labs	7
Food & Environment	5
Others	9

HPLC market expected to grow at 12%

- K V Venugopalan, president, Waters India *An electronics engineer, with MBA degree in marketing, Mr Venugopalan has been associated with Waters India from 1983. He joined Waters as a service engineer in 1983 at Mumbai and rapidly rose to become the Regional Manager in 1986. During 1988, when Waters Corporation set up its joint venture operations in India, he became the general manager for Waters India. When it was decided to make Waters India a 100 percent owned subsidiary during 1997, he became the president with total responsibility for Indian operations.*